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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KINGAN, TIMOTHY G	
ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
05/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,563	PETERS ET AL.	
	Examiner	Art Unit	
	TIMOTHY G. KINGAN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-54* is/are pending in the application.

4a) Of the above claim(s) *28-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/05/2010 has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claim 54** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The inclusion of a capillary stop at the second outlet is not supported in the specification or in the drawings. The specification discloses that the second outlet 13 discharges to the environment [0026].

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. **Claims 51-53** are rejected under 35 U.S.C. 103(a) as being unpatentable over S.E. McBride, U.S. Patent 6,395,232 (herein after McBride) in view of C.C. Karp, U.S. Patent Application Publication 2003/0005967 (herein after Karp).

For Claims 51-53, McBride teaches a microfluidic fluid delivery and distribution system having a fluid input (abstract), **46** coupled to a reservoir **14** and a main channel **48** which in turn has various branches **50** (col 5, lines 36-47; Figs. 5-7) (first channel with one inlet, divided into sections defined by branch channels, equivalent to applicant's second channels, each second channel branching off from the first channel at a branch point, the branch points located sequentially along the first channel; each second channel having a predetermined volume forming a discrete flow path). Further, the branch channels **50** each have an outlet comprising a capillary break **56** (col 5, lines 49-51 Figs. 5-7) (a stopping means at the outlet of the second channels and the inlet of each of the third channels; see below for McBride's third channels).

McBride does not teach the first channel has one outlet. However, McBride does teach that the main channel may be provided with a second input **46"** to overcome the pressure drop from the input to the branch points (col 6, lines 28-32). Examiner notes that such second input may also function as an outlet of the first channel. Moreover, use of such single outlets of main channels in fluid distribution systems comprising sequential branched channels is known in the art. Karp teaches systems for metering

microfluidic volumes (abstract) comprising a single outlet port **311** serving a trunk channel **313** filling branch channels **314** ([0055]; Fig. 1A). It would have been obvious to one of ordinary skill in the art to use an outlet in order to provide an adequate vent for gas being pushed through the main channel as it is filled with fluid from the reservoir.

McBride does not specifically teach each successive second channel fills before the following second channel <u>owing to its greater capillary force</u> with respect to the first channel. However, McBride does disclose that fluids may be moved through the fluidic system by draining or capillary action, as well as pumping (col 4, lines 25-28) (second channels have a greater capillary force than the third channels). Further, McBride teaches the second channels fill sequentially from the closest to the most distant with respect to the fluid input (col 5, lines 62-65) (a second channel begins filling when the second channel connected to a preceding branch point is completely filled). Applicant's greater capillarity at the branch points appears to be an inherent property of McBride's channel system, since fluid is directed to second channels instead of continuing in the first channel, a straight line fluid path.

While McBride and Karp do not specifically teach the capillarity in the area of the outlet of the first channel with respect to its inlet, as noted above, McBride does teach that force in fluid flow may be provided by capillary action. It would have been obvious to one of ordinary skill in the art to use capillarity at the outlet at least as great as that at the inlet in order to promote complete filling of the main channel under conditions of low pressure provided at the inlet.

With regard to at least one of the second channels forming a second channel system, McBride teaches that the branches **50** comprise first section **54** and second section arranged at a right angle to **54** (forming a recess or cavity in the second channel), and a third short section (second and third sections not labeled) leading to the capillary break **56** (at least one of the second channels divided into sections ending at a means for stopping a liquid flow) (Figs. 5-7). McBride does not teach the capillarity of said sections in comparison to that at the branch point. However, in view of McBride's teaching that the low pressure subsystem supplying the branch channels is insufficient to break the capillary break **56** (col 5, lines 60-61), it would have bee obvious to one of ordinary skill in the art to provide for at least the same or increasing capillarity in order to ensure continuous flow up to the break. The only alternative, an increased capillarity, would be counterintuitive to one of ordinary skill in the art, since it might prevent filling of the second channels. Finally, it appears that a change in capillarity is not required in the device of McBride, which relies on a low pressure subsystem for transport to reaction wells **52** (col 5, lines 52-56). Such consideration would suggest to one of ordinary skill in the art that the compared capillarities may be equal.

With regard to third channels, McBride teaches that following each branch channel **54** is a capillary break **56**, beyond which flow continues to a reaction well **52** (col 5, lines 40-42) (third channel) and then to an outlet (Figs. 5-7) (a plurality of third channels provided with an inlet and outlet, each third channel downstream from one of said second channels).

Further for Claim **52** with regard to third channels, McBride teaches fluid from the capillary breaks **56** enters the reaction wells **52** (col 5, lines 62-67; Figs. 6 and 7) (each third channel connected to a separate stopping means) and that the reaction wells each have an outlet (Figs. 5-7) (each third channel has a second outlet wherein the liquid exiting each outlet does not mix with that of other outlets).

3. **Claim 54** is rejected under 35 U.S.C. 103(a) as being unpatentable over McBride in view of Karp and R.E. Pelrine and R.D. Kornbluh, U.S. Patent Application Publication 2003/0141473 (herein after Pelrine).

For Claim 54, McBride teaches a microfluidic fluid delivery and distribution system having a fluid input (abstract), **46** coupled to a reservoir **14** and a main channel **48** which in turn has various branches **50** (col 5, lines 36-47; Figs. 5-7) (first channel with one inlet, divided into sections defined by branch channels, equivalent to applicant's second channels, each second channel branching off from the first channel at a branch point, the branch points located sequentially along the first channel; each second channel having a predetermined volume forming a discrete flow path). Further, the branch channels **50** each have an outlet comprising a capillary break **56** (col 5, lines 49-51 Figs. 5-7) (a stopping means at the outlet of the second channels and the inlet of each of the third channels; see below for McBride's third channels).

McBride does not teach the first channel has one outlet. However, McBride does teach that the main channel may be provided with a second input **46"** to overcome the pressure drop from the input to the branch points (col 6, lines 28-32). Examiner notes

that such second input may also function as an outlet of the first channel. Moreover, use of such single outlets of main channels in fluid distribution systems comprising sequential branched channels is known in the art. Karp teaches systems for metering microfluidic volumes (abstract) comprising a single outlet port **311** serving a trunk channel **313** filling branch channels **314** ([0055]; Fig. 1A). It would have been obvious to one of ordinary skill in the art to use an outlet in order to provide an adequate vent for gas being pushed through the main channel as it is filled with fluid from the reservoir.

McBride does not specifically teach each successive second channel fills before the following second channel owing to its greater capillary force with respect to the first channel. However, McBride does disclose that fluids may be moved through the fluidic system by draining or capillary action, as well as pumping (col 4, lines 25-28) (second channels have a greater capillary force than the third channels). Further, McBride teaches the second channels fill sequentially from the closest to the most distant with respect to the fluid input (col 5, lines 62-65) (a second channel begins filling when the second channel connected to a preceding branch point is completely filled). Applicant's greater capillarity at the branch points appears to be an inherent property of McBride's channel system, since fluid is directed to second channels instead of continuing in the first channel, a straight line fluid path.

While McBride and Karp do not specifically teach the capillarity in the area of the outlet of the first channel with respect to its inlet, as noted above, McBride does teach that force in fluid flow may be provided by capillary action. It would have been obvious to one of ordinary skill in the art to use capillarity at the outlet at least as great as that at

the inlet in order to promote complete filling of the main channel under conditions of low pressure provided at the inlet.

With regard to at least one of the second channels forming a second channel system, McBride teaches that the branches **50** comprise first section **54** and second section at right angle, forming a recess or cavity in the second channel, and a third short section (both not labeled) leading to the capillary break **56** (at least one of the second channels divided into sections ending at a means for stopping a liquid flow) (Figs. 5-7). McBride does not teach the capillarity of said sections in comparison to that at the branch point. However, in view of McBride's teaching that the low pressure subsystem supplying the branch channels is insufficient to break the capillary break **56** (col 5, lines 60-61), it would have bee obvious to one of ordinary skill in the art to provide for at least the same or increasing capillarity in order to ensure continuous flow up to the break. The only alternative, an increased capillarity, would be counterintuitive to one of ordinary skill in the art, since it might prevent filling of the second channels. Finally, it appears that a change in capillarity is not required in the device of McBride, which relies on a low pressure subsystem for transport to reaction wells **52** (col 5, lines 52-56). Such consideration would suggest to one of ordinary skill in the art that the compared capillarities may be equal.

With regard to third channels, McBride teaches that beyond each branch channel **54** is a capillary break **56**, beyond which flow continues to a reaction well **52** (col 5, lines 40-42) (third channel) and then to an outlet (Figs. 5-7) (a plurality of third channels

provided with an inlet and outlet, each third channel downstream from one of said second channels).

Further with regard to third channels, McBride teaches fluid from the capillary breaks **56** enters the reaction wells **52** (col 5, lines 62-67; Figs. 6 and 7) (each third channel connected to a separate stopping means) and that the reaction wells each have an outlet (Figs. 5-7) (each third channel has a second outlet wherein the liquid exiting each outlet does not mix with that of other outlets).

With regard to the cover, McBride teaches that the microfluidic device **16** comprises a top layer **7** which serves as a cover for the device, apertures **13** in layer **8** of which lead to the micro-channel **48** with its branch channels (second channels) (col 3, lines 38-45; Figs. 2 and 5-7) (the microfluidic arrangement has a cover).

Further with regard to third channels, McBride teaches fluid from the capillary breaks **56** enters the reaction wells **52** (col 5, lines 62-67; Figs. 6 and 7) (each third channel connected to a separate stopping means) and that the reaction wells each have an outlet (Figs. 5-7) (each third channel has a second outlet wherein the liquid exiting each outlet does not mix with that of other outlets).

McBride is silent on limitations that channels are arranged as grooves or troughs in a surface covered by a cover. While the channel system of McBride is arranged in the distribution plate **8** with inlets from the top or sample plate, which also serves as a cover, and outlet to the bottom or well plate, McBride is not specific on the alternative configurations including of 1) orienting channels of the system as grooves or troughs in a surface or as a tube passing through, rather than in, a surface. However, the

configuration of arranging channels as grooves in a surface is known in the art. Pelrine teaches fluid-transporting features associated with microfluidic application comprise channels formed as an open groove or trench in a surface [0034] formed by any method known in the art [0048], and that channels may support a fluid distribution system comprising channels that branch successively from a main channel [0006]. It would have been obvious to one of ordinary skill in the art to use, and with reasonable expectation of success, such configuration of grooves in a surface, according to the teaching of Pelrine, as one of a limited number of alternative and equivalent configurations in serving fluid distribution, in order to provide a conventional orientation of possible reaction chambers close to a surface that may be easily visually monitored through a transparent cover.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY G. KINGAN whose telephone number is (571)270-3720. The examiner can normally be reached on Monday-Friday, 8:30 A.M. to 5:00 P.M., E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TGK /Jill Warden/
Supervisory Patent Examiner, Art Unit 1797